

(1) *Amount.* For *Babesia caballi* infections, use intramuscularly 2 milligrams of imidocarb base per kilogram of body weight, repeating dosage once after 24 hours. For *Babesia equi* infections, use 4 milligrams of imidocarb base per kilogram of body weight, repeating dosage four times at 72-hour intervals.

(2) *Indications for use.* For the treatment of babesiosis (piroplasmosis) caused by *Babesia caballi* and *Babesia equi*.

(3) *Limitations.* Administer intramuscularly in the neck region. Do not inject intravenously. Do not use for other equidae or for animals of other species. Do not use in horses less than 1 year old. Do not use for animals in near-term pregnancies. Imidocarb dipropionate is a cholinesterase inhibitor. Do not use this product simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Do not use in horses intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Imidocarb dipropionate is sold only under permit issued by the Director of the National Program Planning Staff, Veterinary Services, APHIS, USDA, to licensed or full-time State, Federal, or military veterinarians.

[43 FR 40455, Sept. 12, 1978, as amended at 46 FR 48642, Oct. 2, 1981; 61 FR 8873, Mar. 6, 1996; 62 FR 61625, Nov. 19, 1997]

§ 522.1156 Imidocarb dipropionate solution.

(a) *Specifications.* Each milliliter of injectable solution contains 120 milligrams of imidocarb.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use—(1) Dogs—(i) Amount.* 6.6 milligrams imidocarb per kilogram (3 milligrams per pound) of body weight.

(ii) *Indications for use.* Treatment of clinical signs of babesiosis and/or demonstrated *Babesia* organisms in the blood.

(iii) *Limitations.* Use subcutaneously or intramuscularly. Not for intravenous use. Repeat the dose after 2 weeks for a total of two treatments.

Imidocarb is a cholinesterase inhibitor. Do not use simultaneously with or a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[62 FR 66984, Dec. 23, 1997]

§ 522.1160 Insulin.

(a) *Specifications—(1) Each milliliter (mL) of porcine insulin zinc suspension contains 40 international units (IU) of insulin.*

(2) Each mL of protamine zinc recombinant human insulin suspension contains 40 IU of insulin.

(b) *Sponsors.* See sponsors in § 510.600 of this chapter for use as in paragraph (c) of this section.

(1) No. 000061 for use of product described in paragraph (a)(1) of this section as in paragraphs (c)(1), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

(2) No. 000010 for use of product described in paragraph (a)(2) of this section as in paragraphs (c)(2)(i)(B), (c)(2)(ii), and (c)(2)(iii) of this section.

(c) *Conditions of use—(1) Dogs—(i) Amount.* Administer an initial once-daily dose of 0.5 IU per kilogram of body weight by subcutaneous injection concurrently with or right after a meal. Adjust this once-daily dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained. Twice-daily therapy should be initiated if the duration of insulin action is determined to be inadequate. If twice-daily treatment is initiated, the two doses should be 25 percent less than the once daily dose required to attain an acceptable nadir.

(ii) *Indications for use.* For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in dogs with diabetes mellitus.

(iii) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats—(i) Amount—(A) Porcine insulin zinc.* Administer an initial dose of 1 to 2 IU by subcutaneous injection. Injections should be given twice daily at approximately 12-hour intervals. For cats fed twice daily, the injections

should be concurrent with or right after a meal. For cats fed ad libitum, no change in feeding is needed. Adjust the dose at appropriate intervals based on clinical signs, urinalysis results, and glucose curve values until adequate glycemic control has been attained.

(B) *Protamine zinc recombinant human insulin*. Administer an initial dose of 0.1 to 0.3 IU/pound of body weight (0.2 to 0.7 IU/kilogram) every 12 hours. The dose should be given concurrently with or right after a meal. Re-evaluate the cat at appropriate intervals and adjust the dose based on both clinical signs and glucose nadirs until adequate glycemic control has been attained.

(ii) *Indications for use*. For the reduction of hyperglycemia and hyperglycemia-associated clinical signs in cats with diabetes mellitus.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[69 FR 25827, May 10, 2004, as amended at 73 FR 21042, Apr. 18, 2008; 74 FR 61517, Nov. 25, 2009; 74 FR 66048, Dec. 14, 2009]

§ 522.1182 Iron injection.

(a) *Specifications*. See § 510.440 of this chapter. Each milliliter (mL) of solution contains the equivalent of:

(1) 100 milligrams (mg) of elemental iron derived from:

- (i) Ferric hydroxide;
- (ii) Ferric oxide; or
- (iii) Elemental iron.

(2) 200 mg of elemental iron derived from ferric hydroxide.

(b) *Sponsors and conditions of use*. It is used in baby pigs by sponsors in § 510.600(c) of this chapter as follows:

(1) Nos. 042552 and 059130 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For prevention of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of iron deficiency anemia, inject 100 mg (1 mL) by intramuscular injection. Dosage may be repeated in approximately 10 days.

(2) No. 000856 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of anemia due to iron deficiency, administer an ini-

tial intramuscular injection of 100 mg at 2 to 4 days of age. Dosage may be repeated in 14 to 21 days.

(ii) For the treatment of anemia due to iron deficiency, administer an intramuscular injection of 200 mg.

(3) Nos. 000061 and 062408 for use of product described in paragraph (a)(1)(i) of this section as follows:

(i) For the prevention of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 150 mg of elemental iron to animals from 1 to 3 days of age.

(ii) For the treatment of iron deficiency anemia, administer intramuscularly an amount of drug containing 100 to 200 mg of elemental iron per animal. Dosage may be repeated in 10 days to 2 weeks.

(4) Nos. 051311 and 053501 for use of product described in paragraph (a)(1)(ii) of this section as follows:

(i) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(ii) For treatment of iron deficiency anemia, administer 1 to 2 mL by intramuscular injection at 5 to 28 days of age.

(5) No. 053501 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular or subcutaneous injection up to 4 weeks of age.

(6) Nos. 058005 and 059130 for use of product described in paragraph (a)(1)(iii) of this section as follows:

(i) For prevention of anemia due to iron deficiency, administer 100 mg by intramuscular injection at 2 to 4 days of age.

(ii) For treatment of anemia due to iron deficiency, administer 100 mg by intramuscular injection. Treatment may be repeated in 10 days.

(7) Nos. 042552 and 059130 for use of product described in paragraph (a)(2) of this section as follows:

(i) For prevention of baby pig anemia due to iron deficiency, intramuscularly